



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,526	08/24/2006	Tatsuhiko Kodama	295060US0PCT	9779
22850 7590 10/02/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WANG, CHANG YU	
			ART UNIT 1649	PAPER NUMBER
			NOTIFICATION DATE 10/02/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/590,526	Applicant(s) KODAMA ET AL.	
	Examiner Chang-Yu Wang	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/24/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/24/06, 11/23/07</u> . | 6) <input checked="" type="checkbox"/> Other: <u>notice of sequence noncompliance</u> . |

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 because 37CFR 1.821 (a)(2)(c-d) states that each sequence disclosed must appear separately in the "sequence listing" and in the text of the description and claims whenever described. For example, no valid CRF is provided for SEQ ID NOs:1 & 2 listed on p. 7 and for SEQ ID NOs: 3 & 4 on p. 36 of the specification. See MPEP § 2422 & 2431. Applicant needs to provide a computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). Appropriate correction is required.

Status of Application/Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1-7) in the reply filed on 7/2/08 is acknowledged.

Claims 1-11 are pending. Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no

Art Unit: 1649

allowable generic or linking claim. In addition, claim 8 is also withdrawn from further consideration because claim 8 is directed to a diagnostic agent, which is a non-elected invention of Group II. Claim 8 was erroneously included in the Group I in the office action of restriction requirement mailed 1/2/08. Election was made **without** traverse in the reply filed on 7/2/08. In addition, claims 4-7 are improper multiple dependent claims and thus have not been further treated on the merits. Claims 1-3 are under examination in this office action.

Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

5. Claim 1 is objected to because of the following informalities: PTX3 is not a common abbreviation in the art. Applicants are required to spell out PTX3 at the first usage. Appropriate correction is required.

6. Claims 4-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-7 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to determine a grade of

Art Unit: 1649

vascular injury and how to determine the severity of the disease based on “a grade” since the grade is not defined in the claims. No specific or defined or standard level of PTX3 is recited in the claims. Thus, a skilled artisan cannot determine or assess a grade of vascular injury.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite because claim 1 recites “a grade”. The rest of claims are indefinite as depending from an indefinite claim 1. The claims are drawn to assessing a grade of vascular injury. However, the disclosure fails to set forth the metes and bounds of what is encompassed within the definition of “a grade” and thus the claims are indefinite.

In addition, claims 1-3 are indefinite because of the term “PTX3” recited in the claims without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: or providing a full name for abbreviated names. Without identification of property or combination of properties which are unique to and, therefore, definitive of the instant recitations, the metes and bounds of the claims remain undetermined. Further, the use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the

Art Unit: 1649

claims to specifically and uniquely identify PTX3, for example, by SEQ ID NO. and function of PTX3.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosis of coronary artery condition (CA), unstable angina (UAP) and myocardial infarction (AMI) by measuring an increased level of PTX3 using an anti-PTX antibody as compared to defined controls, does not reasonably provide enablement for a method for assessing an undefined grade of vascular injury or determining an undefined heart disease or cerebrovascular disease by determining the level of PTX3 as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

“There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is ‘undue’. These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G)

The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

Breath of the claims: Claims 1-3 are drawn to a method of assessing a grade of vascular injury by determining the level of PTX3 in a test sample wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease. The claims encompass detection and diagnosis of all forms of vascular injury, all forms of heart diseases and all forms of cerebrovascular diseases by measuring the level of PTX3, which is not supported by the instant specification or the prior art. In addition, the claims encompass an undefined grade or standard to determine all forms of diseases or the severity of the diseases.

Nature of the invention: The instant invention is based on a finding that blood PTX3 levels are increased in patients suffering from coronary artery condition (CA), unstable angina (UAP) and myocardial infarction (AMI) as compared to defined controls. The instant specification shows that the level of PTX3 in blood is higher in patients suffering from CA, UAP and AMI, and the pathological conditions of these patients are severe as compared patients without CA, UAP and AMI.

State of the prior art/predictability/experimentation: Based on the specification and the prior art, Applicant is enabled for diagnosis or prognosis of coronary artery condition (CA), unstable angina (UAP), and acute myocardial infarction (AMI) by detecting an increased PTX3 level with an anti-PTX3 antibody. However, the claims are not limited to the diseases and the detection method as set forth above. The

Art Unit: 1649

specification fails to demonstrate that all forms of heart diseases and vascular injury have a common correlation and thus can be detected by the same method. The specification also fails to establish a correlation between CA/UAP/AMI and all forms of cerebrovascular diseases. Thus, it is unpredictable whether an increased level of PTX3 can be applied to diagnosis of all forms of vascular injury, heart diseases and all forms of cerebrovascular diseases. Applicant is not enabled for diagnosis of all forms of heart diseases or vascular injury or any form of cerebrovascular disease using the claimed method because different diseases have different causes.

In addition, the specification fails to provide sufficient guidance as to what levels of PTX3 correlate with what degrees of vascular injury, a specific form of heart disease or cerebrovascular disease in a specific manner. The specification provides no standard to determine a grade of vascular injury or severity of heart disease or cerebrovascular disease. Thus, a skilled artisan cannot contemplate what level of PTX3 can be considered as what grade of vascular injury and further to determine how severe the disease is.

Therefore, in view of the breadth of the claims, the lack of sufficient guidance in the specification, the unpredictability of the invention, and the current status of the prior art, undue experimentation would be required by a skilled artisan to perform in order to practice the claimed invention.

9. Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 1649

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 1-3 are drawn to a method of assessing a grade of vascular injury by determining the level of PTX3 in a test sample wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease. The claims encompass a genus of vascular injury, a genus of heart diseases and a genus of cerebrovascular diseases. However, the specification only describes coronary artery condition (CA), unstable angina (UAP), and acute myocardial infarction (AMI) that can be detected in the method and only teaches detection of an increased PTX3 level with an anti-PTX3 antibody but fails to teach other heart diseases or vascular injury or other detection methods that can be used in the claimed method. But, the claims are not limited to the diseases and detection methods as set forth above.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand

Art Unit: 1649

what Applicant is in possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of a method of detecting an increased level of PTX3 using an anti-PTX3 antibody in patients suffering from CA, UAP, and AMI. Applicant is not in possession of detecting other vascular injury or heart diseases or cerebrovascular diseases. The instant specification fails to provide sufficient descriptive information to support that the claimed method can be used to assess all forms of vascular injury or all forms of heart diseases or cerebrovascular diseases. In addition, the prior art does not provide compensatory correlative teachings sufficient to enable one of skill to use for all the claimed diseases. Since no common characteristics/features of all forms of vascular injury, heart or cerebrovascular diseases are known, a skilled artisan cannot envision the functional correlations of the genus of diseases with the claimed invention. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of diseases.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until

Art Unit: 1649

reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, a method of assessing a grade of vascular injury by determining the level of PTX3 has not met the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement. See MPEP § 2163.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1649

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peri et al. (Circulation. 2000, 102:636-641 as in IDS).

Claims 1-3 are drawn to a method of assessing a grade of vascular injury by determining the level of PTX3 in a test sample wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease.

Peri et al. teach a method of using PTX3 as an early indicator of myocardial infarction in human, which meets the limitations as recited in instant claims 1-3 (see p. 636, abstract). Peri et al. teach that PTX3 plasma concentrations are higher in patients suffering from acute myocardial infarction, which is myocyte irreversible injury in ischemic cardiomyopathy (i.e. a condition of vascular injury as in instant claim 1 and is a heart disease as in instant claim 2) (see p. 637, 1st col.-2nd col.). Peri et al. teach detection of PTX3 plasma concentrations via an ELISA method using an anti-PTX3 antibody (see p. 637, 2nd col.-p. 638, 1st col.). Thus, Claims 1-3 are anticipated by Peri et al..

11. Claims 1-3 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by US2004/0137544 (Latini et al., published Jul 15, 2004, priority Oct 31, 2002).

Claims 1-3 are drawn to a method of assessing a grade of vascular injury by determining the level of PTX3 in a test sample wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease.

US2004/0137544 teaches a method of diagnosing a cardiovascular and cerebrovascular disease (i.e. vascular injury) by detecting an increased level of PTX3 in patient's plasma, which meets the limitations as recited in instant claims 1-3 (see p. 1, [0004]-[0009]). US2004/0137544 teaches a method of diagnosing patients with myocardial infarction (i.e. heart disease) or cerebral ictus (i.e. cerebrovascular disease) by measuring the plasmatic level of PTX3 via an immunoassay method with an anti-PTX3 antibody (see p. 1, [0004]-[0010]; p. 2, example 2). US2004/0137544 teaches that an increased level of PTX3 in patients' plasma is an indicator of risk of death or complications for the diseases. Thus, Claims 1-3 are anticipated by US2004/0137544.

12. Claims 1-3 are rejected under 35 U.S.C. 102 (a) as being anticipated by Latini et al. (Circulation 2004, 110:2349-2354, as in IDS).

Claims 1-3 are drawn to a method of assessing a grade of vascular injury by determining the level of PTX3 in a test sample wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease.

Art Unit: 1649

Latini et al. disclose a method of detecting an increased level of PTX3 in acute myocardial infarction, which is a condition of vascular injury, as recited in instant claims 1-3 (see p. 2349, abstract; p. 2350, 1st col., 3rd-4th paragraphs; p. 2352, 1st col., 1-3rd paragraphs). Latini et al. teach detection of an increased level of PTX3 in blood of patients suffering from heart failure, cardiac ischemia and acute coronary syndrome as compared to controls (see p. 2350, 1st col., 3rd-4th paragraphs). Heart failure, cardiac ischemia and acute coronary syndrome are heart diseases and a form of vascular injury. Latini et al. also teach the test sample is blood (see p. 2350, 1st col. 4th paragraph). The level of PTX3 in blood is detected via a ELISA method using an anti-PTX3 antibody (see p. 2350, 1st col. 4th paragraph). Latini et al. teach the increased level of PTX3 in blood can be a prognostic marker for the above heart diseases (see p. 2352, 1st col.) Thus, Claims 1-3 are anticipated by Latini et al..

Obviousness-Type Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 12/092272. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-3 encompass a method of assessing a grade of vascular injury by determining the level of PTX3 including detecting the level of PTX3 with an anti-PTX3 antibody. Claims 1-3 of the '272 application encompass a method of determining the severity of mild vasculopathy by measuring the level of PTX3 with an anti-PTX3 antibody. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite the same method steps and are directed to achieving the same goal to determine or assess a vascular disease by detection of the level of PTX3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. NO CLAIM IS ALLOWED.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 1649

Rolph et al. (Arterioscler. Thromb . Vasc. Biol. 2002. p.e10-e14, as in IDS) teach production of the long Pentraxin PTX3 in advanced atherosclerotic plaques.

Fazzini et al. (Arthritis & Rheumatism 2001. 44: 2841-2850, as in IDS) teach elevated concentrations of PTX in patients with vasculitis.

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/

Chang-Yu Wang, Ph.D.

September 15, 2008

/Christine J Saoud/

Primary Examiner, Art Unit 1647